DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 17, 2014

Ceragem International, Inc.
% E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K140592
Trade/Device Name: Ceragem Automatic Thermal Massager, Model CGM-MB-1101
Regulation Number: 21 CFR 890.5880
Regulation Name: Multi-Function Physical Therapy Table
Regulatory Class: Class II
Product Code: JFB
Dated: November 17, 2014
Received: November 17, 2014

Dear E.J. Smith,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140592

Device Name
Ceragem Automatic Thermal Massager, Model CGM-MB-1101

Indications for Use *(Describe)*
The intended use of the Ceragem® Thermal Massager Model CGM-MB-1101 Automatic Thermal Massager is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:
- Temporary relief of minor muscle and joint pain stiffness
- Temporary relief of minor joint pain associated with arthritis
- Temporary increase in local circulation where applied
- Relaxation of muscles

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

807.92(c)

Sponsor:	Ceragem International, Inc.	807.92(a)(1)
Address:	3699 Wilshire Blvd., 930 Los Angeles, CA 90010	
Contact Person:	Raymond Chung	
Phone:	213-480-7070	
Fax:	213-341-2338	
Summary Prepared:	November 11, 2014	

Device Name: 807.92(a)(2)

Trade Name:	Ceragem Automatic Thermal Massager Model CGM-MB-1101
Common/Usual Name:	Massage Table
Classification Name:	Table, Physical Therapy, Multi-Function
Establishment Registration Number:	2087361
Product Code:	JFB
Device Classification:	Class II
Regulation Number:	21 CFR 890.5880

Predicate Device: 807.92(a)(3)

Manufacturer	Brand Name	510(k) Number
Ceragem International, Inc.	CERAGEM-C Thermal Massager	K040031

Device Description 807.92(a)(4)

This device is comprised of the main body and optional components. The main body components are the main mat which includes the internal projector and the up/down movement motor, and the lower mat. The optional components are the external projectors (3-sphere and 9-sphere). This device is an electrically powered, motorized, multi-functional physical therapy table intended to use for temporary relief of muscle and joint pain and stiffness by applying massage pressure from the vertical and horizontal movements, and heat from the internal and external projectors.

Indications for Use 807.92(a)(5)

The intended use of the Ceragem® Thermal Massager Model CGM-MB-1101 Automatic Thermal Massager is to provide muscle relaxation therapy by delivering heat and soothing massage. Additionally, the product provides topical radiant infrared heat for:

- Temporary relief of minor muscle and joint pain stiffness
- Temporary relief of minor joint pain associated with arthritis
- Temporary increase in local circulation where applied
- Relaxation of muscles

12.3 Predicate Product Comparison Chart 807.92(a)(6)

		Predicate Device	Subject Device
Device Brand Name and Manufacturer		CERAGEM-C Thermal Massager Ceragem International, Inc.	**CGM MB-1101** Automatic Thermal Massager Ceragem International, Inc.
510(k) Number		K040031	
Rated Voltage		AC 120V 60Hz	100-127Vac 50/60Hz
Operation Power		Maximum 280 Watts	360 VA 240 Watts]
Home Use		Yes	Yes
Style		Flood Model (Massage Bed)	Flood Model (Massage Bed)
Remote Control		Yes	Yes
Operation Method		Auto / Manual	Auto / Manual
Emission Source		Jade Projectors	Jade Projectors
Infrared Emission Spectrum		Jade: 5 ~ 20 Epoxy Carbon Panel: 5 ~ 20	Jade: 5 ~ 20 Epoxy Carbon Panel: 5 ~ 20
Heating Lamp	Voltage	12V	24Vdc
	Power	10W	15W
Operating Temperature Range		30°C – 60°C (86°F – 140°F)	1. Internal : 30°C – 65°C (86°F – 149°F) 2. External, main, Auxiliary : 30°C – 60°C (86°F – 140°F)
Extra Overheating Protection		Yes	Yes
Moving Device		Geared DC Motor	Geared DC Motor
Limit Detector		Limit Switch	Limit Switch
Temperature Sensor		Temperature Coefficient Variable Resistor	Thermistor
Control Method		Microchip's Microcontroller	Microchip's Microcontroller
Tugging Method		Wire-Chain	Wire-Chain
Material	Support Frame	Steel	Steel, ABS
	Massager Cover	Vinyl	Polyester, Cotton, Rayon, Poly urethane
	Cover Sheet	Cotton	Oxford
	Rails	Ergonomically Molded Polyethylene	Ergonomically Molded Polyethylene
Internal Projector		Ergonomic Tilting Jade Rollers	Ergonomic Tilting Jade Rollers
Jade Heads	Internal Projector	1 Jade Ball in the Middle 4 Jade Rollers (Total of 5)	1 Jade Ball in the Middle 4 Jade Rollers (Total of 5)
	External Projectors	Three (3) Jade Heads Projector Nine (9) Jade Heads Projector	Three (3) Jade Heads Projector Nine (9) Jade Heads Projector
Mat Dimensions		1920mm x 550mm x 130mm 76 in x 22 in x 5 in (L x W x H)	1. When spread out : 700㎜×2016㎜×450㎜(±5mm) 2. When folded : 700㎜×1258㎜×450㎜(±5mm)
Weight		Approximately 38 Kg (84 lb.)	Main body: 23kg(±2kg)

		Sliding support: 14kg(±2kg) Frame: 16kg(±2kg)
Patient Population	Adult	Adult

12.4 Differences Table

		Predicate Device	Subject Device	Difference
Rated Voltage		AC 120V 60Hz	100-127Vac 50/60Hz	Changed SMPS (**switched-mode power supply)**
Operation Power		Maximum 280 Watts	360 VA [240 Watts]	Changed SMPS (**switched-mode power supply)**
Heating Lamp	Voltage	12V	24Vdc	Changed the heating element
	Power	10W	15W	
Operating Temperature Range		30°C – 60°C (86°F – 140°F)	1. Internal : 30°C – 65°C (86°F – 149°F) 2. External, main, Auxiliary : 30°C – 60°C (86°F – 140°F)	Changed internal temperature range
Temperature Sensor		Temperature Coefficient Variable Resistor	Thermistor	No changes
Material	Support Frame	Steel	Steel, ABS	Added new components
	Massager Cover	Vinyl	Polyester, Cotton, Rayon, Poly urethane	Changed components
	Cover Sheet	Cotton	Oxford	Changed components
	Rails	Ergonomically Molded Polyethylene	Ergonomically Molded Polyethylene	
Mat Dimensions		1920mm x 550mm x 130mm 76 in x 22 in x 5 in (L x W x H)	1. When spread out : 700㎜×2016㎜×450㎜ (±5mm) 2. When folded : 700㎜×1258㎜×450㎜	New design (Sliding in/out structure)

		(±5mm)	
Static Weight	300	298 pounds	Substantially Equivalent
Maximum Permissible Weight	300	298 pounds	Substantially Equivalent
Weight	Approximately 38 Kg (84 lb.)	Main body: 23kg(±2kg) Sliding support: 14kg(±2kg) Frame: 16kg(±2kg)	Changed design

12.4 Discussion of Technological Characteristics 807.92(b)(1)

Both CGM MB-1101 and the predicate device use massage rollers and heat to provide muscle relaxation therapy. The CGM MB-1101 emits topical radiant infrared heat in the range of 5-20 microns from the jade massage rollers, heated by lamps located inside the rollers. The predicate device also emits topical heat through lamps located in the jade massage rollers in the range of 5-20 microns. Both the CGM MB-1101 device and the predicate provide the massage component by attaching the jade rollers to a carriage mounted under a padded cushion that traverses the torso. The CGM MB-1101 device also transmits heat through the two Epoxy Carbon Panels and an infrared-rays heating element. While the predicate device does not include Epoxy Carbon Panels, the maximal heat of the CGM MB-1101 remains lower than that of the predicate. Additionally, both CGM MB-1101 and the predicate device have been tested to and meet the following standards:

1. UL 60601-1, 1st Edition, 2006-04-26 (include National Differences for USA)
2. CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
3. IEC 60601-1:2005 + CORR.1 (2006) + CORR.2 (2007)
4. EN 60601-1:2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
5. IEC 60601-1-2: 2007 Medical Electrical Equipment Part 1-2: General Requirements for Electromagnetic Compatibility
6. IEC 62304 Medical device Software – Software Life Cycle Processes
7. ISO 10993-10 Biological Evaluation of medical Devices – Part 10: Tests for Irritation and Skin Sensitization
8. ISO 14971 Medical Devices – Application of Risk Management to Medical Devices

12.5 Conclusions 807.92(b)(3)

Based on comparison of the CGM Mb-1101 to the predicate device, we conclude that the CGM MB-1101 has the same intended use, indications for use, and intended population, and similar

functional and performance characteristics. The addition of the two Epoxy panels and one infrared-rays heating element does not raise new safety or effectiveness issues since the temperature never exceeds the maximal temperature of the predicate device. Other visual distinctions do not impact safety or effectiveness.